

## § 3415.8

### § 3415.8 Other Federal statutes and regulations that apply.

Several other Federal statutes and regulations apply to grant preproposals or proposals considered for review or to grants awarded under this part. These include but are not limited to:

- 7 CFR 1.1—USDA implementation of the Freedom of Information Act;
- 7 CFR Part 1c—USDA implementation of the Federal Policy for the Protection of Human Subjects;
- 7 CFR Part 3—USDA implementation of OMB Circular A-129 regarding debt collection;
- 7 CFR Part 15, Subpart A—USDA implementation of title VI of the Civil Rights Act of 1964;
- 7 CFR Part 520—ARS implementation of the National Environmental Policy Act;
- 7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (*i.e.*, Circular Nos. A-110, A-21, and A-122) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly, the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance;
- 7 CFR Part 3016—USDA Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments;
- 7 CFR Part 3017, as amended—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants);
- 7 CFR Part 3018—USDA implementation of New Restrictions on Lobbying. Imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans;
- 7 CFR Part 3051—Audits of Institutions of Higher Education and Other Nonprofit Institutions;
- 7 CFR Part 3407—NIFA implementation of the National Environmental Policy Act;
- 29 U.S.C. 794, section 504—Rehabilitation Act of 1973, and 7 CFR Part 15B (USDA implementation of the statute), prohibiting discrimination based upon physical or mental handicap in Federally assisted programs;
- 35 U.S.C. 200 *et seq.*—Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR part 401).

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### § 3415.9 Other conditions.

The Director or Administrator may elect to use a portion of available funding each fiscal year to support an Annual Conference, the purpose of which will be to bring together scientists and regulatory officials relevant to this program. At the Annual Conference, the participants may offer individual opinions regarding research needs, update information and discuss progress, or may offer individual opinions on areas of risk assessment research appropriate to agricultural biotechnology. The annual program solicitation will indicate whether funds are available to support an Annual Conference and, if so, will include instructions on the preparation and submission of proposals requesting funds from the Department for support of an Annual Conference. The Department may also elect to require principal investigators whose research is funded under this program to attend an Annual Conference and to present data on the results of their research efforts. Should attendance at an Annual Conference be required, the annual program solicitation will so indicate, and principal investigators may include attendance costs in their proposed budgets.

The Director or Administrator may, with respect to any grant or to any class of awards, impose additional conditions prior to or at the time of any award when, in the Director's or Administrator's judgment, such conditions are necessary to ensure or protect advancement of the approved project, the interests of the public, or the conservation of grant funds.

### Subpart B—Scientific Peer Review of Research Grant Applications

#### § 3415.10 Establishment and operation of peer review groups.

Subject to § 3415.5, the Director or Administrator shall adopt procedures for the conduct of peer reviews and the formulation of recommendations under § 3415.14.

#### § 3415.11 Composition of peer review groups.

(a) Peer review group members and *ad hoc* reviewers will be selected based

upon their training and experience in relevant scientific or technical fields, taking into account the following factors:

(1) The level of formal scientific or technical education by the individual and the extent to which an individual is engaged in relevant research activities;

(2) The need to include as peer reviewers experts from various areas of specialization within relevant scientific or technical fields;

(3) The need to include as peer reviewers experts from a variety of organizational types (e.g., universities, Federal laboratories, industry, private consultant(s), Federal and State regulatory agencies, environmental organizations) and geographic locations; and

(4) The need to maintain a balanced composition of peer review groups related to minority and female representation and an equitable age distribution.

(b) [Reserved]

#### § 3415.12 Conflicts of interest.

Members of peer review groups covered by this part are subject to relevant provisions contained in title 18 of the United States Code relating to criminal activity, Departmental regulations governing employee responsibilities and conduct (part O of this title), and Executive Order No. 11222, as amended.

#### § 3415.13 Availability of information.

Information regarding the peer review process will be made available to the extent permitted under the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a.), and implementing Departmental regulations (part 1 of this title).

#### § 3415.14 Proposal review.

(a) All grant applications will be acknowledged. Prior to technical examination, a preliminary review will be made for responsiveness to the program solicitation (e.g., relationship of application to announced program area). Proposals that do not fall within the guidelines as stated in the program solicitation will be eliminated from competition and will be returned to the applicant.

(b) All applications will be carefully reviewed by the Director or Administrator, qualified officers or employees of the Department, the respective peer review group, and *ad hoc* reviewers, as required. Written comments will be solicited from *ad hoc* reviewers when required, and individual written comments and in-depth discussions will be provided by peer review group members prior to recommending applications for funding. Applications will be ranked and support levels recommended within the limitation of total available funding for each research program area as announced in the program solicitation.

(c) No awarding official will make a grant based upon an application covered by this part unless the application has been reviewed in accordance with the provisions of this part and unless said reviewers have made recommendations concerning the scientific merit and relevance to the program of such application.

(d) Except to the extent otherwise provided by law, such recommendations are advisory only and are not binding on program officers or on the awarding officials of NIFA and ARS.

#### § 3415.15 Evaluation factors.

In carrying out its review under § 3415.14, the peer review group will take into account the following factors unless, pursuant to § 3415.5(a), different evaluation criteria are specified in the annual program solicitation:

(a) Scientific merit of the proposal.

(1) Conceptual adequacy of hypothesis;

(2) Clarity and delineation of objectives;

(3) Adequacy of the description of the undertaking and suitability and feasibility of methodology;

(4) Demonstration of feasibility through preliminary data;

(5) Probability of success of project;

(6) Novelty, uniqueness and originality; and

(7) Appropriateness to regulation of biotechnology and risk assessment.

(b) Qualifications of proposed project personnel and adequacy of facilities.

(1) Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record